

Claims:

We claim

- 5 1. An article of manufacture comprising a polysiloxane rubber substrate and a lubricious silane copolymer coating wherein the copolymer coating forms a layer covering the surface of the rubber substrate.
- 10 2. The article of Claim 1 wherein the substrate is a medical device.
3. The article of Claim 2 wherein the medical device is a catheter.
- 15 4. The article of Claim 1 wherein the lubricious silane copolymer coating is the reaction product of one or more polyisocyanates with one or more lubricious polymers having at least two functional groups, which may be the same or different, that are
20 reactive with isocyanate, and with one or more organo-functional silanes having at least two functional groups, which may be the same or different, that are reactive with isocyanate, and at least one functional group reactive with a silicone rubber substrate.
- 25 5. A process for preparing a silane copolymer comprising reacting one or more polyisocyanates with one or more lubricious polymers having at least two functional groups, which may be the same or different, that are reactive with an isocyanate functional

group and with one or more organo-functional silanes having at least two functional groups, which may be the same or different, that are reactive with an isocyanate functional group, and at least one functional group reactive with a silicone rubber substrate.

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6. The process of Claim 5 further comprising the addition of a solvent.

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7. The process of Claim 5 further comprising the addition of a catalyst.

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8. The process of Claim 7 wherein the catalyst is selected from the group consisting of N,N-dimethylaminoethanol, N,N-dimethyl-cyclohexamine-bis(2-dimethyl aminoethyl) ether, N-ethylmorpholine, N,N,N',N',N''-pentamethyl-diethylene-triamine, 1-2(hydroxypropyl) imidazole, stannous octoate, dibutyl tin dilaurate, dioctyltin dilaurate, dibutyl tin mercaptide, ferric acetylacetonate, lead octoate, and dibutyl tin diricinoleate.

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9. The process of Claim 5 wherein the polyol is a diol.

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10. The process of Claim 9 wherein the diol is selected from the group consisting of poly(ethylene adipates), poly(diethyleneglycol adipates), polycaprolactone diols, polycaprolactone-polyadipate copolymer diols, poly(ethylene-terephthalate)diols, polycarbonate diols, polytetramethylene ether glycol, polyethylene glycol, ethylene oxide adducts of polyoxypropylene diols, and ethylene oxide adducts of polyoxypropylene triols.

11. The process of Claim 10 wherein the polyethylene glycol is a low molecular weight polyethylene glycol.

5 12. The process of Claim 11 wherein the low molecular weight polyethylene glycol is Carbowax 1450.

13. The process of Claim 10 wherein the polyethylene glycol is a higher molecular weight polyethylene glycol.

10 14. The process of Claim 5 wherein the polyisocyanate is a diisocyanate.

15 15. The process of Claim 14 wherein the diisocyanate is selected from the group consisting of 4,4'-diphenylmethane diisocyanate and position isomers thereof, 2,4- and 2,6-toluene diisocyanate (TDI) and position isomers thereof, 3,4-dichlorophenyl diisocyanate, dicyclohexylmethane-4,4'-diisocyanate (HMDI), 4,4'-diphenylmethane diisocyanate (MDI), 1,6-hexamethylene diisocyanate (HDI) and position isomers thereof, isophorone diisocyanate (IPDI), and adducts of diisocyanates.

20 16. The process of Claim 15 wherein the diisocyanate is dicyclohexylmethane-4,4'-diisocyanate (HMDI).

25 17. The process of Claim 5 wherein the organo-functional silane is an amino-functional alkoxysilane.

18. The process of Claim 17 wherein the amino-functional alkoxysilane is N-(2-aminoethyl)-3-aminopropyl-methyldimethoxy silane.

5 19. The process of Claim 5 wherein the polyisocyanate is dicyclohexylmethane-4,4'-diisocyanate (HMDI), the amino-functional alkoxysilane is N-(2-aminoethyl)-3-aminopropyl-methyldimethoxy silane, and the polyol is Carbowax 1450.

10 20. The process of Claim 5 comprising the steps of

(a) reacting one or more polyols with an excess of polyisocyanate in the presence of a catalyst to form a polyurethane-urea prepolymer having terminal isocyanate groups;

15 (b) reacting the prepolymer formed in step (a) with one or more organo-functional silanes having at least two functional groups, which may be the same or different, that are reactive with the isocyanate groups on the polyurethane-urea prepolymer and at least one functional group reactive with a silicone rubber substrate to form a silane copolymer; and

20 (c) optionally stabilizing the copolymer formed in step (b) by treating the copolymer with an alcohol.

21. The process of Claim 20 wherein step (a) further comprises the addition of a solvent.

25 22. The process of Claim 20 wherein the catalyst is selected from the group consisting of N,N-dimethylaminoethanol, N,N-dimethyl-cyclohexamine-bis(2-dimethyl aminoethyl) ether, N-

ethylmorpholine, N,N,N',N',N''-pentamethyl-diethylene-triamine, 1-2(hydroxypropyl) imidazole, stannous octoate, dibutyl tin dilaurate, dioctyltin dilaurate, dibutyl tin mercaptide, ferric acetylacetonate, lead octoate, and dibutyl tin diricinoleate.

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23. The process of Claim 20 wherein the polyol is a diol.

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24. The process of Claim 23 wherein the diol is selected from the group consisting of , poly(ethylene adipates), poly(diethyleneglycol adipates), polycaprolactone diols, polycaprolactone-polyadipate copolymer diols, poly(ethylene-terephthalate)diols, polycarbonate diols, polytetramethylene ether glycol, polyethylene glycol, ethylene oxide adducts of polyoxypropylene diols, and ethylene oxide adducts of polyoxypropylene triols.

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25. The process of Claim 24 wherein the polyethylene glycol is a low molecular weight polyethylene glycol.

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26. The process of Claim 25 wherein the low molecular weight polyethylene glycol is Carbowax 1450.

27. The process of Claim 24 wherein the polyethylene glycol is a higher molecular weight polyethylene glycol.

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28. The process of Claim 20 wherein the polyisocyanate is a diisocyanate.

29. The process of Claim 28 wherein the diisocyanate is selected from the group consisting of 4,4'-diphenylmethane diisocyanate and position isomers thereof, 2,4- and 2,6-toluene diisocyanate (TDI) and position isomers thereof, 3,4-dichlorophenyl diisocyanate, dicyclohexylmethane-4,4'-diisocyanate (HMDI), 4,4'-diphenylmethane diisocyanate (MDI), 1,6-hexamethylene diisocyanate (HDI) and position isomers thereof, isophorone diisocyanate (IPDI), and adducts of diisocyanates.

30. The process of Claim 29 wherein the diisocyanate is dicyclohexylmethane-4,4'-diisocyanate (HMDI).

31. The process of Claim 20 wherein the organo-functional silane is an amino-functional alkoxysilane.

32. The process of Claim 31 wherein the amino-functional alkoxysilane is N-(2-aminoethyl)-3-aminopropyl-methyldimethoxy silane.

33. The process of claim 5 comprising the steps of

(a) reacting one or more organo-functional silanes having at least two functional groups, which may be the same or different, that are reactive with an isocyanate functional group and at least one functional group reactive with a silicone rubber substrate with an excess of polyisocyanate to form a polyurea prepolymer having terminal isocyanate groups;

(b) reacting the polyurea prepolymer formed in step (a) with one or more polyols in the presence of a catalyst to form a silane copolymer; and

(c) optionally stabilizing the copolymer formed in step (b) by treating the copolymer with an alcohol.

34. The process of Claim 33 wherein step (a) further comprises the addition of a solvent.

35. The process of Claim 33 wherein the catalyst is selected from the group consisting of N,N-dimethylaminoethanol, N,N-dimethyl-cyclohexamine-bis(2-dimethyl aminoethyl) ether, N-ethylmorpholine, N,N,N',N',N''-pentamethyl-diethylene-triamine, 1-2(hydroxypropyl) imidazole, stannous octoate, dibutyl tin dilaurate, dioctyl tin laurate, dibutyl tin mercaptide, ferric acetylacetonate, lead octoate, and dibutyl tin diricinoleate.

36. The process of Claim 33 wherein the polyol is a diol.

37. The process of Claim 36 wherein the diol is selected from the group consisting of , poly(ethylene adipates), poly(diethyleneglycol adipates), polycaprolactone diols, polycaprolactone-polyadipate copolymer diols, poly(ethylene-terephthalate)diols, polycarbonate diols, polytetramethylene ether glycol, polyethylene glycol, ethylene oxide adducts of polyoxypropylene diols, and ethylene oxide adducts of polyoxypropylene triols.

38. The process of Claim 37 wherein the polyethylene glycol is a low molecular weight polyethylene glycol.

39. The process of Claim 38 wherein the low molecular weight polyethylene glycol is Carbowax 1450.

40. The process of Claim 37 wherein the polyethylene glycol is a higher molecular weight polyethylene glycol.

41. The process of Claim 33 wherein the polyisocyanate is a diisocyanate.

42. The process of Claim 41 wherein the diisocyanate is selected from the group consisting of 4,4'-diphenylmethane diisocyanate and position isomers thereof, 2,4- and 2,6-toluene diisocyanate (TDI) and position isomers thereof, 3,4-dichlorophenyl diisocyanate, dicyclohexylmethane-4,4'-diisocyanate (HMDI), 4,4'-diphenylmethane diisocyanate (MDI), 1,6-hexamethylene diisocyanate (HDI) and position isomers thereof, isophorone diisocyanate (IPDI), and adducts of diisocyanates.

43. The process of Claim 42 wherein the polyisocyanate is dicyclohexylmethane-4,4'-diisocyanate (HMDI).

44. The process of Claim 33 wherein the organo-functional silane is an amino-functional alkoxysilane.

45. The process of Claim 44 wherein the amino-functional alkoxy silane is N-(2-aminoethyl)-3-aminopropyl-methyldimethoxy silane.

5 46. A silane copolymer comprised of one or more polyisocyaantes, one or more organo-functional silanes, and one or more polyols.

10 47. The silane copolymer of Claim 46 comprised of dicyclohexylmethane-4,4'-diisocyanate (HMDI), N-(2-aminoethyl)-3-aminopropyl-methyldimethoxy silane, and Carbowax 1450.

48. A lubricious coating comprising a silane copolymer.

15 49. The coating of Claim 48 wherein the silane copolymer is a polyurethane-urea-silane copolymer.

20 50. The coating of Claim 48 wherein the coating further comprises a hydrophilic polymer.

25 51. The coating of Claim 50 wherein the hydrophilic polymer is selected from the group consisting of polyethylene oxide (PEO), polyethylene glycol (PEG), polysaccharides, hyaluronic acid and its salts and derivatives, sodium alginate, chondroitin sulfate, celluloses, chitin, chitosan, agarose, xanthans, dermatan sulfate, keratin sulfate, emulsan, gellan, curdlan, amylose, carrageenans, amylopectin, dextrans, glycogen, starch, heparin sulfate, and limit

dextrins and fragments thereof; synthetic hydrophilic polymers, poly(vinyl alcohol), and poly(N-vinyl) pyrrolidone (PVP).

5 52. A lubricious coating comprising a primer coat containing a silane copolymer and top coat.

10 53. The coating of Claim 52 wherein the primer coat is the reaction product of one or more polyisocyanates, one or more organo-functional silanes having at least two functional groups, which may be the same or different, that are reactive with isocyanate and at least one functional group reactive with a silicone rubber substrate, and a low molecular weight polyethylene glycol.

15 54. The coating of Claim 53 wherein the low molecular weight polyethylene glycol is Carbowax 1450.

20 55. The coating of Claim 52 wherein the top coat is the combination of a high molecular weight polyethylene oxide and a reactive mixture of polyfunctional isocyanate and polyol.

25 56. The coating of Claim 52 wherein the top coat is the combination of a polyvinyl pyrrolidone and a reactive mixture of polyfunctional isocyanate and polyol.

57. The coating of Claim 52 wherein the top coat is the reaction product of one or more polyisocyanates, one or more organo-functional silanes having at least two functional groups, which

may be the same or different, that are reactive with isocyanate and at least one functional group reactive with a silicone rubber substrate, and a higher molecular weight polyethylene glycol.

- 5 58. The coating of Claim 57 wherein the higher molecular weight polyethylene glycol is Carbowax 8000.